

## REMARKS

### I. INTRODUCTION

The instant invention is directed to an apparatus for facilitating the delivery and deployment of an endovascular support device or stent to a predetermined location within the vascular system. More specifically, the invention, *inter alia*, secures the stent to the balloon of a balloon catheter without the need for a deployment sheath. Thus, reducing the profile of the delivery system. The invention also includes a balloon having at least three wrapped and folded wings to provide for symmetrical expansion and deployment of the stent.

The invention is manufactured such that the balloon protrudes through and surrounds portions of the stent conforming to the generally tubular shape thereof. The stent itself being retained in indentations formed in the balloon during the manufacturing process.

Notwithstanding Applicants' contribution to this field and significant improvement over the prior art, claims 1-4 [sic] and 12 stand rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent Number 5,445,646 issued to Euteneuer *et al.* (hereinafter "Euteneuer"). Claims 5-11 [sic] and 13-15 stand withdrawn from consideration as being drawn to a non-elected invention.<sup>1</sup>

Applicants have amended the claims under consideration and added new claims to more distinctly claim what Applicants regard as their invention. And to more particularly distinguish between the cited prior art and the claimed invention. New claims 16-32 are readable on the elected invention of Group I.

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<sup>1</sup> Claims 1-7 and 12 are drawn to the invention of Group I. See Office Action dated September 27, 1996. Therefore, for the purposes of this response, it is assumed that claims 5-7 were intended to be included within the rejection under 35 U.S.C. 102.

## II. EUTENEUER DOES NOT ANTICIPATE THE CLAIMED INVENTION

To anticipate a claim, "the reference must teach every aspect of the claimed invention . . ."

M.P.E.P. § 706.02(a); see also M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

Euteneuer discloses a self-expanding stent delivery apparatus. Self-expanding stent 17 is carried by catheter 12. And is held in place, or confined, on catheter 12 by water soluble bands 18. A pair of slipping sleeves 14, 16 act as a waterproof sheath isolating the water soluble retaining bands 18 from exposure to bodily fluids until it is desired to deploy the self-expanding stent 17.

To deploy stent 17, slipping sleeves 14, 16 are inflated via inflation ports 36, 38. As fluid pressure builds in slipping sleeves 14, 16, fluid is forced out through seal 30 causing seal 30 to slide away from the self-expanding stent 17 along catheter 12, thereby retracting slipping sleeves 14, 16 exposing stent 17 and water soluble retaining bands 18 to body fluids. Bands 18 dissolve and stent 17 expands into engagement with the vessel wall.

As-filed independent claims 1 and 12 recited either the stent to be encapsulated by the balloon, as in claim 1, or the endovascular support device be encapsulated by the balloon catheter, as in claim 12. The term "encapsulated," in the context of the present invention, refers to the balloon being formed to partially surround and adhere to the stent. *See, e.g.*, the specification at page 4, lines 10-12, and page 9, lines 4-6. This feature is nowhere shown nor suggested by

Euteneuer.

Euteneuer does not disclose a balloon or a balloon catheter. Moreover, Euteneuer teaches away from one of the stated objectives of the instant invention *i.e.*, an improved stent delivery system which does not require a sheath during delivery. Slipping sleeves 14, 16, of Euteneuer, act as a sheath during delivery, thereby increasing the profile of the system and its ability to navigate tortuous vasculature.

Notwithstanding the foregoing, Applicants have amended claims 1 and 12 to recite that the stent is mounted on a balloon of a balloon catheter and secured thereto by encapsulation by the balloon. And added independent claims 17 and 24 which call for the balloon to partially surround the stent thereby securing it to the balloon for intraluminal delivery.

Regarding various other aspects of the invention set forth in the dependent claims, Euteneuer does not teach or suggest: the stent to be formed of a plurality of substantially straight segments connected at axial bends; a balloon formed from a plurality of wings (Euteneuer as pointed out above, does not even disclose a balloon); the balloon forming the retaining means; or the stent being retained in indentations in the balloon.

Accordingly, claims 1-7, 12 and 16-32 are considered to patentably define over the teachings of Euteneuer.

### **III. REMAINING PRIOR ART**

The other reference cited by the Examiner is U.S. Patent Number 5,571,135 issued to Fraser *et al.* ("Fraser"). Fraser discloses a self-expanding stent delivery system similar to

Euteneuer. Therefore, Fraser is considered to be no more pertinent to Applicants' claimed invention than Euteneuer, and patentable there over for the same reasons discussed above with reference to Euteneuer.

Applicants also bring to the Examiner's attention the following patents cited in the corresponding PCT application:

U.S. Patent Number 5,108,416 issued to Ryan *et al.*;

U.S. Patent Number 5,158,548 issued to Lau *et al.*; and

U.S. Patent Number 5,158,548 issued to Lau *et al.*

These references are noted on the attached PTO-Form 1449. And copies are provided for the Examiner's convenient reference.

#### IV. CONCLUSION


For the foregoing reasons, it is submitted that claims 1-7, 12 and 16-32 are not anticipated nor suggested by Euteneuer. Accordingly, reconsideration and allowance of the instant application is respectfully solicited.

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Respectfully submitted,

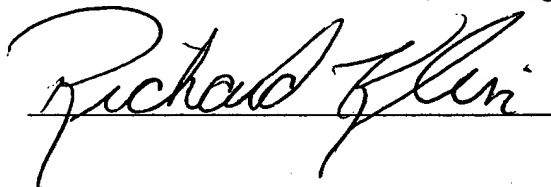
  
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